FBI Laboratory
Practices for Developing Methods and Validating Technical Procedures

1 Purpose

These practices establish the requirements for developing new methods and provide direction for validating technical procedures prior to those procedures being introduced into casework and DNA databasing. Method development is the acquisition and evaluation of test data for the determination of conditions and/or limitations of a novel method to achieve consistent results. Validation is the process for determining whether specified requirements are adequate for an intended use. If a new method is intended to be used for casework or DNA databasing, then it must be validated according to this practice. Refer to Appendix A for an overview of the steps required for developing methods and validating technical procedures. These practices also satisfy the requirements of the FBI Laboratory Quality Assurance Manual and the applicable accrediting body(ies).

2 Scope

These practices apply to FBI Laboratory personnel who are authorized to develop, modify, verify, and validate new methods and technical procedures that pertain to casework or DNA databasing. These methods and technical procedures may be developed internally or externally.

3 Practices

3.1 Method Development

Method development is the acquisition and evaluation of test data for the determination of conditions and/or limitations of a method to achieve consistent results. Development must be a planned activity and recorded. The plan must be approved by the Technical Leader. If the Technical Leader is the preparer, another qualified and authorized individual will approve the plan. Any changes to the plan will be communicated to all personnel involved in developing the method. External standard methods previously utilized for forensic applications that do not require modification may proceed to the validation phase.

3.1.1 Personnel must record and/or reference any other technical work relied upon in the method development process. Such records may include publications, presentations at scientific meetings, symposia, or research studies generated by the FBI Laboratory or an external laboratory.

3.2 Method Development Review

3.2.1 The Technical Leader will evaluate the developed method to ensure it is fit for the intended purpose.

3.2.2 The Technical Leader will record agreement with the developed method with their name, signature, and date of the review. If the Technical Leader developed the method, another qualified and authorized individual will approve it.

3.2.3 Any resulting method that will be used for casework and/or DNA databasing will be validated prior to being used.

3.3 Validation

All proposed technical procedures must be validated in the FBI Laboratory prior to use for casework and DNA databasing. Prior to beginning a validation study, a plan of action will be prepared and recorded. The Technical Leader will approve the validation plan prior to beginning the validation study. If the Technical Leader is the preparer, another qualified and authorized individual will approve the plan.

3.3.1 The validation plan will include the test method(s), specific equipment, and sample preparation techniques(s) to be used, if necessary. Further, it will record the validation requirements of the procedure. The validation plan will provide direction for the activities that will be performed and acceptance criteria for the validation.

3.3.2 Appropriate level 2 documents will define and/or reference the minimum requirements for a validation study. The validation study will include:

- Identifying the limitations of the procedure, reported results, opinions, and interpretations.
- Conditions under which reliable results can be obtained.
- Critical aspects of the procedure that must be controlled and monitored.
- The scope and accuracy of the procedure to meet the needs of the given application.
- The associated data analysis and interpretation.
- Establishing the data required to report a result, opinion, or interpretation.

3.3.3 When validating a procedure, known samples must be used.

3.3.4 Prior to applying a procedure to casework or DNA database samples, validation records must demonstrate the procedure performs as expected, or with modification performs as expected, in the FBI Laboratory.

3.3.5 Validation of chemical procedures must additionally meet the requirements of the Laboratory Operations Manual (LOM) - Practices for Validating Chemical Procedures.

3.4 Validation Review and Records

3.4.1 Once the validation study has been completed a validation summary will be prepared.

3.4.2 The applicable Unit Chief(s) and Technical Leader will evaluate the results of the validation study and the validation summary before the procedure is used in the FBI Laboratory. If the Technical Leader is the preparer, another qualified and authorized individual will evaluate the results. These persons will record agreement with the validation results and summary with their signature and the date of the review.

3.4.3 Once the validation study has been completed and evaluated as described in section 3.4.2, the technical procedure will be written according to the LOM - Practices for Writing Technical Procedures if it will be used for casework or DNA databasing.

3.4.4 When a technical procedure is written following validation, a Quality Assurance reviewer will ensure the validation records are complete prior to the procedure being approved according to the LOM - Practices for Document Control.

3.4.5 Previously Validated Procedure

When a previously validated procedure is to be used in a new facility, a simplified validation will be required to ensure technically sound results can be produced. The appropriate Unit Chief(s) and Technical Leader will record agreement with the validation results with their signature and the date of the review before implementing the procedure. If the Technical Leader is the preparer, another qualified and authorized individual will record agreement with the validation results.

3.5 Resolution of Disagreement

If a disagreement arises between the parties involved in developing a new method or validating a procedure and an agreement cannot be reached, resolution will be achieved following the LOM - Practices for Resolution of Scientific or Technical Disagreement.

3.6 Competency Tests

3.6.1 After the validation process on a technical procedure is completed, each examiner and/or technician who will apply the new procedure to casework or DNA databasing must successfully complete a competency test prior to applying the new procedure to casework or DNA databasing. This test will demonstrate the examiner and/or technician can accurately perform the technical procedure. For personnel involved in the validation process, the Unit Chief and the Technical Leader may approve the validation to serve as demonstration of competency for personnel involved in the validation. This approval will be recorded.

3.6.2 Additional authorization records will be generated, when applicable.

3.6.3 Newly validated procedures will be incorporated into the proficiency testing program, when applicable.

3.7 Procedure Modifications

There are times when deviating from an established technical procedure is necessary. Changes to or deviations from a procedure must be within the bounds of good laboratory practice, recorded, justified, and authorized according to the LOM - Practices for Authorizing Deviations. Modifications to validated chemical procedures have additional requirements as listed in LOM - Practices for Validating Chemical Procedures.

3.7.1 If a significant modification (significance is determined by the Technical Leader in the appropriate discipline/category of testing) needs to be made to a previously validated procedure, the influence of such changes will be evaluated. Where the changes are determined to affect the original validation, a new validation will be performed. Results generated by means of the change will be evaluated through comparison to the results generated using the current procedure, to include using the appropriate samples. These modifications should produce results of the same or improved quality as compared with those obtained by the previously validated procedure, or adequate for the intended use.

3.7.2 A minor modification to an existing procedure that is not expected to materially affect the performance of the test does not require additional validation studies. These modifications may affect the efficiency, effectiveness, and/or quality of the test without affecting the results. Minor modifications will be handled as minor or major deviations, as appropriate, and requested and authorized according to the LOM - Practices for Authorizing Deviations.

3.7.3 All modifications will be made available to personnel within a discipline and/or category of testing to maintain consistency when others are faced with the same or similar circumstances.

3.7.4 When a modification becomes routine (routine being determined by the Technical Leader in the appropriate discipline and/or category of testing), the technical procedure will be revised according to the LOM - Practices for Writing Technical Procedures and the LOM - Practices for Document Control.

3.8 Record of Method Development and Validation

Appropriate level 2 documents will provide instructions regarding where the records for the reviews, approvals, development, and validation will be retained.

4 Records

The following records are generated and/or permanently retained as a result of these practices:

- All records related to developing a method and the associated reviews.

- All records related to the validation study including the study plan, the results, and the associated reviews.
- A summary of the validation.
- All competency test records including approvals for the validation to serve as demonstration of competency.
- Additional authorization records, when applicable.

5 References

FBI Laboratory Operations Manual, Federal Bureau of Investigation, Laboratory Division, latest revision.

FBI Laboratory Quality Assurance Manual, Federal Bureau of Investigation, Laboratory Division, latest revision.

ISO/IEC 17025 - General Requirements for the Competence of Testing and Calibration Laboratories, International Organization for Standardization, Geneva, Switzerland, 2017.

ISO/IEC 17025:2017 - Forensic Science Testing and Calibration Laboratories Accreditation Requirements (AR 3125), ANAB, Milwaukee, WI, April 29, 2019.

Quality Assurance Standards for Forensic DNA Testing Laboratories, Federal Bureau of Investigation, July 1, 2020.

Quality Assurance Standards for DNA Databasing Laboratories, Federal Bureau of Investigation, July 1, 2020.

Rev. #	Issue Date	History
6	06/03/19	Modified definition of validation in Section 1. Updated section 2 to reflect that personnel must be authorized to develop, modify, verify, and validate methods and procedures in casework and DNA databasing. Removed validation definition from section 3.3. Expanded validation study requirements in section 3.3.2. Modified section 3.4.3 and flowchart in Appendix A to reflect review performed by Technical Leader. Revised requirements related to significant modifications in section 3.7.1. Updated section 3.8 to cover all types of reviews. Updated list of references in section 5.
7	12/21/20	Grammatical and editing changes made throughout for clarity Replaced: forensic examinations or examination of evidence with casework throughout Replaced: SOPs with technical procedures throughout Added: If the TL is the preparer, another qualified and authorized individual will complete the task throughout 1 – Added: DNA databasing 3.1 – Removed: language regarding novel methods 3.2.2 – Removed: initials 3.3 – Replaced: review with approve 3.3.1 – Added: validation 3.3.3 and 3.3.4 – Removed: novel or existing 3.4.2 – Removed: initials; Added: applicable 3.4.3 – Replaced: reviewed by the Technical Leader, and approved with and evaluated as described in section 3.4.2 3.4.4 – Added: following validation 3.4.5 – Removed: initials if the Technical Leader is the preparer, another qualified and authorized individual will record agreement with the validation results 3.6.1 – Added: for personnel involved in the validation 3.8 – Replaced: Procedure with Method 4 – Added: A summary of the validation 5 – Added: LOM and updated dates

Approval

Redacted - Signatures on File

Laboratory Director Date: 12/18/2020

Quality Manager Date: 12/18/2020

Appendix A: *Flowchart for Developing Methods and Validating Technical Procedures*

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